REMARKS

I. STATUS OF CLAIMS

Upon entry of the amendments provided herein, claims 1, 3-6, 9-37, 39-42, and 44-77 are pending; claims 1, 3, 5, 16, 20-27, 30, 32-35, 40, 41, 48-51, 56-61, 65, and 72-77 are amended, and claims 2, 7-8, 38 and 43 are herein canceled without prejudice and/or disclaimer.

Amendments to independent claims 1, 30, and 65 are supported by original claim 2. Additional amendments to claims 1, 5, 16, 20-27, 30, 32-35, 40, 41, 48-51, 56-61, 65, and 72-77 are made to correct a minor typographical error in the chemical name of mecamylamine. Specifically, references to N-2,**2**,3-tetramethylbicyclo-[2.1.1]heptan-2-amine have been corrected to recite N-2,**3**,3-tetramethylbicyclo-[2.1.1]heptan-2-amine. That correction would have been obvious to a person of ordinary skill in the art as the Merck Index confirms that the full chemical name of mecamylamine is N-2,**3**,3-tetramethylbicyclo-[2.1.1]heptan-2-amine. Moreover, the correct name is identified in the specification at least in the title of the present invention and at paragraph [012]. It is also noted that submitted herewith is a Substitute Specification under 37 C.F.R. § 1.125(b), which corrects this typographical error in the specification.

Claim 3 is amended to correct the dependency, as claim 2 is now canceled. Accordingly, no new matter is added by those amendments to the claims.

II. OBJECTION UNDER 37 C.F.R. § 1.75(c)

The Office maintained the objection to claims 38-51 under 37 C.F.R. § 1.75(c) as being in improper dependent form, i.e., failing to further limit the subject matter of the

previous claim. Office Action at page 2. In particular, the Office contends that "[c]laims 39-42 and 44-51 . . . recite an intended use without reciting a specific chemical or physical property of the formulation of claim 30 from which they depend." *Id.* Applicant continues to respectfully disagree for the reasons of record and for the additional reasons provided below.

Based on the Office's rationale, "a specific chemical or physical property of the formulation" must be included in the dependent claims in order for such claims to further limit the subject matter of the previous claim. Office Action at page 2. However, each of claims 39-42 and 44-51 expressly recites a further limitation to the respective claim from which it depends.

For example, as provided in dependent claim 39, it further recites a particular side effect that is minimized with the administration of the modified release formulation of the present invention in comparison to the administration of a conventional formulation of N-2,3,3-tetramethylbicyclo-[2.1.1]heptan-2-amine, or a pharmaceutically acceptable salt thereof in comparison to the recited a modified-release formulation. Likewise, dependent claims 40 and 41 further define the time period of the maximum plasma concentration; dependent claim 42 further defines the administration period; dependent claims 44 and 45 further define the peak:trough plasma ratio; dependent claims 46 and 47 further define the plasma concentration; and dependent claims 48 and 49 further define the plasma concentration.

As such, Applicant submits that claims 39-42 and 44-57 recite further limitations on a physical property of the formulation of claim 30 from which they all directly or

indirectly depend. Thus, Applicant respectfully requests that this objection be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office maintained the rejection of claims 1-29 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Office Action at page 2. In response to Applicant's arguments, the Office asserts that: (1) there are no working examples; (2) there is no support for minimizing side effects such as heart rate, blurred vision, bladder function or blood pressure; (3) hypothetical situations are only present; and (4) there are no noted conclusions with respect to minimizing and reducing side effects or gastrointestinal motility caused by any pathological condition. *Id.* at page 3. Based on that evidence, the Office concludes that "the skilled artisan in gastroenterology would reasonably require a more detailed description of both disease states characterized by gastrointestinal hypermotility, that are encompassed by the language of claim 1, and of minimization of side effects." *Id.* at page 4. Applicant continues to respectfully disagree and traverses the rejection for the reasons of record and for those found below.

The Office again focuses the Section 112, first paragraph, rejection on the lack of working examples and the use of hypothetical examples. Office Action at page 3. As admitted at page 3 of the Office Action, the presence or absence of a working example is not the standard by which compliance with Section 112, first paragraph is judged. All that is required is that the specification reasonably convey to one of ordinary skill in the art that as of the filing date of the application, applicant was in possession of the present invention; how the specification shows possession is immaterial. *See In re Kaslow*, 707

F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). Thus, Applicant's lack of working examples and use of hypothetical examples does not evidence a lack of written description.

Under the written description standard, the Office has the initial burden of presenting by a preponderance of the evidence why a person of ordinary skill in the art would not recognize in applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1970). Merely stating that "a more detailed description of both diseases characterized by gastrointestinal hypermotility" and "minimization of side effects" is required misconstrues the written description requirement by not addressing why a more detailed description is necessary for a skilled artisan. In fact, the Office's comment that "the specification fails to provide *support* for reducing gastrointestinal [motility]" further evidences that misunderstanding, as it is not whether *support* such as a working example is provided but whether a person of ordinary skill in the art would recognize the applicant's disclosure as a description of the claimed invention. Office Action at page 4 (emphasis added).

Moreover, the Office's contention that "the broad language of the claims encompasses essentially any bowel motility disorder regardless of the etiology of the disease process" again ignores the objective standard for determining written description. Given the amendments provided herein directed to particular gastrointestinal motility disorders, that contention is moot, as the claims now recite specific gastrointestinal motility disorders.

Applicant submits that claims 1-29 statisfy the written description requirement under 35 U.S.C. § 112, first paragraph. Accordingly, Applicant respectfully requests the withdrawal of that rejection.

IV. REJECTION UNDER 35 U.S.C. § 103

The Office maintained the rejection of claims 1-77 under 35 U.S.C. § 103(a) as unpatentable over WO 00/35280 to Shytle et al. or WO 00/35279 to Shytle et al. (since both references are related and share a common disclosure, reference herein to "Shytle" encompasses both of the two references). Office Action at page 4. In response to Applicant's arguments, the Office continues to assert that Shytle teaches compositions comprising racemic (and both isomers) of mecamylamine for the treatment of gastrointestinal motility disorders. *Id.* at page 5. Moreover, the Office contends that "[v]arious dosage forms and dosage ranges, as those presently claimed, are taught by Shytle." *Id.* Applicant continues to respectfully disagree for the reasons of record and to traverse the rejection for the additional reasons provided below.

Shytle recognizes that despite mecamylamine's proven efficacy in the treatment of hypertension, the side effects associated with mecamylamine treatment lead to its "demise as a first line treatment for essential hypertension." Shytle at page 1. For example, the generalized ganglionic blockade results in atony of the bladder and gastrointestinal tract, impaired sexual function, cycloplegia, xerostomic, diminished perspiration, and postural hypotension. *Id.* According to Shytle, better symptom control and fewer side effects are needed for mecamylamine treatment. *Id.* at page 6. To answer such a need, Shylte provides a composition that includes a therapeutically effective amount of exo-R-mecamylamine or a pharmaceutically acceptable salt thereof,

substantially free of exo-S-mecamylamine, in combination with a pharmaceutically acceptable carrier. Shytle at Abstract, 7, and 20-22. In particular, Shytle teachings are directed to mecamylamine treatment for patients with nicotine-responsive neuropsychiatric disorders not gastrointestinal disorders. *Id.* at pages 6 and 7.

In fact, Shytle fails to teach the specific gastrointestinal conditions recited in the amended claims. Even more so, Shytle fails to teach the use of mecamylamine to treat those conditions. In order to establish a *prima facie* case of obviousness, such teachings must be present. M.P.E.P. § 2143. Here, Shytle does not teach all the claim elements.

Moreover, Shytle would teach a person of ordinary skill in the art *away* from mecamylamine to treat those specific gastrointestinal conditions. Shytle describes numerous side-effects associated with the administration of mecamylamine. Shytle at pages 1 and 2. One of which includes gastrointestinal side effects such as atony of the bladder and gastrointestinal tract, abdominal pains, and constipation. Shytle defines side effects as being "unwanted actions which may include . . . constipation . . . and dyspepsia." Shytle at pages 11 and 12. Considering those side effects, a person of ordinary skill in the art would be lead away from using mecamylamine as a treatment for gastrointestinal conditions.

Accordingly, for at least the above-mentioned reasons, Shytle fails to establish a *prima facie* case of obviousness of any of the pending claims and thus, Applicant respectfully requests the withdrawal of the rejection.

V. CONCLUSION

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing the pending claims in condition for allowance. Applicant submits that the proposed amendments to the pending claims do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Finally, Applicant submits that the entry of the amendment would place the application in better form for appeal, should the Examiner continue to dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is not rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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